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KEiTO

Multifunction Keito K6,K 7 & K8

Section 05
510(K) SUMMARY
[21CFR § 807.92 (c)]

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1-Submitter information. [21CFR§807.92(a)]

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2-Name of the Device. [21CFR§807.92(a) (1)]

Bundling considerations:
Because all the models submitted on this 510(k) are sharing the same technology and intended use, we declare that they do not differ significantly in purpose, software design, materials, energy source, function or any other feature. **[21CFR § 860.3]**. All the devices can be managed during one review because the only difference is on the externald esign, even some of them share the same labelling design.

Device Name and Classification:

Common Device Name:	Blood Pressure Monitoring System and Body FatA nalyzer Scales
Trade Names:	Keito K6, Keito K7,K eito K8.
Device Class:	Class II (Two).
Classification Name:	SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE,W EIGHT, HEIGHT, BODY FAT .
Class Code:	DXN:N on Invasive Blood Pressure Measurement **[21CFR§ 870.1130]**. MNW :b ody composition analyzer. **[21CFR§ 870.2770]**.

3-Claiming equivalence with predicates. [21CFR§807.92(a)(3)].

Predicate name	Predicate reference	510(k) code
Vita-Stat	90550-03	K811146
Keito Multifunction	K5	K984083
Tanita corp.	TBF-300	K014009
Omron Health inc.	HBF-306	K011652

Table 1-Predicates we consider equivalence.

4-Description of the Device [21CFR§ 807.92(a)(4)].

The Multifunction Keito K6, K7 & K8 arei ntended for public uset o measureh eight, weight, systolica nd diastolic blood pressures, to calculate pulse rate and body mass, and to estimate the percentage of body fat by using a non-invasive bio impedance analyzer.
The Multifunction Keito K6, K7 & K8 have got 2 coin entries allowing the selection of two operation modes: partialo r totalc ycle of measurements:

- Partial cycle:m easure of weight,h eight and estimation of the body fat.
- Totalc ycle: measure of weight, height, blood pressure,p ulse rate and estimation of the body fat.

4.1-Weight and Height

- If during the measurement theu ser moves, theM ultifunction Keito K6, K7 & K8 will not be able to measure his weight correctly.
- If during the measurementt he user is notu pright, the Multifunction Keito K6, K7 & K8 willn ot be able to measure his real height.T he system measures the total heighti ncluding the user's shoes.

4.2-Blood Pressure

- Before inserting the wristi n the cuff,t he user mustr emove the watch and any bracelet.
- The Multifunction Keito K6, K7 & K8 have got as ystem that detects automatically when the wrist is inserted and leanti n the cuff.
- If fora ny reason the system does not detectt he presence of the wrist in the cuff, the system can be manually activating by pressing the green key att he front of the unit.
- If the blood pressure measure has not started in 60 seconds, the system will cancel the process and will go to the estimation of the body fat .
- For a correctm easuring, the user mustr emain relaxed and mustn ot speak or make sudden movements.
- In case of emergency, by pressing the red key at the front of the unit, the process will be cancelled and the security system will deflate the cuff so that the user can remove his wrist from the cuff. In case of power fail,t he same process will occur automatically.
- If after three tries, the system cannotm easure the blood pressure, the system willg o to the estimation of the body fat .

4.3-Body fat

- Ift he user steps off the platform or does not indicate the age and gender, the measurement of the body fat will be cancelled.
- For ac orrect measurement, it is necessary to hold firmly the handles(that act like electrodes) with the hands bare and clean.
- A bad contact between the handles and the hands may lead to errors in the results of the measurement.

- After a heavy meal or drink, the results may be faulty.

At the end of the measuring process, the Multifunction Keito K6, K7 & K8 prints the results in a ticket.

4.4-Limitations of use:

- If the measured weight is under 15 kg, the system understands that there is a baby on the platform and cancels the measurements of height, blood pressure and body fat .
- If the user's height is under 135 cm, the measurements of blood pressure and body fat will be cancelled.
- In those cases, if the selected measurement cycle was the complete one, the Multifunction Keito K6, K7 & K8 wills how on the tickett hatt he mewasuring process could not be completed.

The Multifunction Keito K6, K7 & K8 calculates the body fat on people whose age is between 20 and 99 years old.

4.5-Physical Characteristics

	K8	K7	K6
Height **Width** **Depth** **Weight**	2200 mm 360 mm 580 mm 46 kg	2200 mm 360 mm 580 mm 46 kg	2200 mm 360 mm 580 mm 46 kg
Main Supply **Consumption** **Main Fuse**	100-240V 50Hz-60Hz 0.160A @ 230V 2A	100-240V 50Hz-60Hz 0.160A @ 230V 2A	100-240V 50Hz-60Hz 0.160A @ 230V 2A
Measurement ranges **Weight** **Height** **Blood pressure** **Heart rate** **Fat**	 0 - 150 kg 0 - 200 cm 0 - 300 mmHg 38 - 176 bpm 1 - 75 %	 0 - 150 kg 0 - 200 cm 0 - 300 mmHg 38 - 176 bpm 1 - 75 %	 0 - 150 kg 0 - 200 cm 0 - 300 mmHg 38 - 176 bpm 1 - 75 %
			
	K8	K7	K6

Table 2-Keito k6, K7 & K8 physicalc haracteristics

4.6-Materials used (in contact with the user):

- The body is made of Linear Polyethylene Plastic (PE-LLD).
- The platform is covered by a rubber mat.
- The handles for the body fate stimation are made of tin plated with chrome.
- The cuff used in the blood pressure measurement: 100% Polyesther horizontal plot.

5-Statement of the Intended Use. [21CFR§807.92(a) (5)].

The Multifunction Keito devices are intended to be used by general public without prescription, operated with coins, to measure personal health parameters such as weight, height, estimation of body fat , blood pressure, and pulse rate. Multifunction Keito can be installed in pharmacies or in other public sites. It is not ad iagnostic device, and only offers data thatu sers can consult with their personalp hysicians. The results are either printed on a ticket or saved on a card.

The differences between the predicates wich we are claiming equivalence are not critical to the intended use of the Keito devices. And these differences do not reduce the safety or the effectiveness of the device while it is being used as it is labelled, or while the voice instructions are being followed.

6-Comparison with the predicates. [21CFR§807.92(a) (6)].

Specifications	MULTIFUNCTION KEITO (K6, K7 & K8)	Vita-Stat 90550-03	Multifunction K5	Tanita TBF-300	Omron HBF-306
Accuracy	Weight: 100 g Height: 1 cm Blood pressure: 1 mmHg Body fat: 0.1 %	Blood pressure: 1 mmHg	Weight: 100 g Height: 1 cm Blood pressure: 1 mmHg	Weight: 100 g Height: 1 cm Body fat: 0.1 %	Body fat: 0.1 %
Digital Displays	Weight, height, blood pressure	blood pressure	Weight, height,b lood pressure, pulse	Weight, body fat	Body fat
Measurement range	Weight: 10 to 150 kg Height: 0 to 200 cm Bloodp ressure: 0 to 300 mmHg Body fat: 1 to 75%	Blood pressure: 0 to 300 mmHg	Weight: 10 a 150 kg Height: 0 to 200 cm Blood pressure: 0 to 300 mmHg	Weight: 0 to 440 lb Height: manual height rod from 3' to 7' Body fat: 1 to 75%	Body fat: 4 to 50%
Blood pressure measurement method	Oscillometric	Oscillometric	Oscillometric	N/A	N/A
Overpressure limit	300 mmHg	305 mmHg	300 mmHg	N/A	N/A
Blood pressure test time	Tipically less than 50 seconds	Tipically less than 30 seconds	Tipically less than 50 seconds	N/A	N/A
Inflation	Compressor, automatically controlled	Compressor, automatically controlled	Compressor, automatically controlled	N/A	N/A
Deflation	Automatic deflation and air exhaust	Automatic deflation and air exhaust	Automatic deflation and air exhaust	N/A	N/A
Rapid pressure release	Security valve. Emergency stop button at front of the unit.		Security valve. Emergency stop button at front of the unit.	N/A	N/A
Pressure detection	Differential pressure sensor		Absolute pressure sensor	N/A	N/A
Cuff dimensions	99 mm diameter		99 mm diameter	N/A	N/A
Wrist / fore arm circumference range	140 to 210 mm (wrist)	(fore arm)	140 to 210 mm (wrist)	N/A	N/A
Body fat measurement method	Bio Impedance Analysis (BIA)	N/A	N/A	Bio Impedance Analysis (BIA)	Bio Impedance Analysis (BIA)
Body fat test time	Tipically less than 10 seconds	N/A	N/A	Tipically less than 10 seconds	Tipically less than 10 seconds
Temperature operating	10°C to 40°C	10°C to 40°C	10°C to 40°C	0°C to 35°C	10°C to 40°C
Input Power requirements	200-240 Vac / 100-120 Vac 50/60 Hz (automatic) 0.16A @ 200-240 Vac / 0.32A @ 100-120 Vac	120 Vac , 60 Hz., 2.5A	200-240 Vac / 100-120 Vac 50/60 Hz (automatic) 0.6A @ 200-240 Vac / 1.2A @ 100-120 Vac	100-240 Vac 50/60 Hz AC adapter	2 "AAA" (R03) batteries
Physical height		1079 mm	2330 mm	–	127 mm
Width		647 mm	540 mm	--	203 mm
Depth		927 mm	590 mm	--	51 mm
Weight		40 kg	60 kg	19.3 kg	0.248 kg

Table 3-Comparison with predicates

7-Clinical tests. [21CFR§807.92(b) (2)].

7.1-Blood Pressure Measurement:

We declare that we are the manufacturero f the predicate Keito K5 (K984083). Therefore, we can assert that the technology and the software on Multifunction Keito K6, K7 & K8 are an evolution of K5 unit. This evolution is not a great change wich can vary the effectiveness or the safety. Some components have been replaced by other technologically more advanced. In order to demonstrate and compare the same efficency, we have performed a clinical testa nd its results have been compared with the results obtained with Keito K5 (K984083).

7.1.1-Multifunction K7 Test Results. (See Section 18.2 of this 510(k) submission).

Sample Data Summary

	Number of Observations	Range Min	Range Max	Mean Difference	SD of Differences	%Exceeding 5 mmHg	%Exceeding 10 mmHg	%Exceeding 15 mmHg
Observer1 - Observer2								
Systolic	267	93	176	-0.4	3.1	7.1%	0.0%	0.0%
Diastolic	267	53	98	-0.4	3.0	8.2%	0.0%	0.0%
Keito K7 - Observers								
Systolic	267	94	174	-0.6	5.2	50.6%	4.1%	0.0%
Diastolic	267	55	98	0.4	4.5	38.2%	1.5%	0.0%
Observer								
Pulse	267	51	113	0				
Keito K7 - Observer								
Pulse	267	51	120	0.9	4.1	27.3%	1.5%	0.0%
	Number of Observations	**Range Min**	**Range Max**	**Average**	**SD**			
Age	89	18	83	46	14.3			
Wrist circumference in cm	89	12	20	15.6	1.5			
Arm circumference in cm	89	21	36	25.9	2.6			
Heigt in cm	267	146	191	167.8	9.7			
	Number of Patients	**Male**	**Female**	**%Male**	**%Female**			
Sex	89	48	41	53.9%	46.1%			

Table 4-TestR esults K7 vs Patient.

7.1.2-Multifunction K5 Test Results. (Submitted on K984083).

Sample Data Summary

	Number of Observations	Range Min	Range Max	Mean Difference	SD of Differences	%Exceeding 5 mmHg	%Exceeding 10 mmHg	%Exceeding 15 mmHg
Observer 1 - Observer 2								
Systolic	267	90	175	0.1	2.7	4.1%	1.9%	0.0%
Diastolic	267	60	105	-0.2	2.3	4.1%	0.0%	0.0%
Keito K5 – Observers								
Systolic	267	90	175	1.0	5.0	30.7%	6.7%	1.5%
Diastolic	267	61	101	-0.7	3.8	23.6%	2.2%	0.0%
Observer								
Pulse	267	57	122	0				
Keito K5 – Observer								
Pulse	267	56	125	-1.4	4.7	24.0%	4.5%	1.9%
	Number of Observations	**Range Min**	**Range Max**	**Average**	**SD**			
Age	89	18	89	51	18.2			
Wrist circumference in cm	89	13	23	17.2	2.0			
Arm circumference in cm	89	21	40	29.0	3.5			
Heigt in cm	267	145	191	170.4	10.4			
	Number of Patients	**Male**	**Female**	**%Male**	**%Female**			
Sex	89	45	44	50.6%	49.4%			

Table 5-TestR esults K5 vs Patient

7.1.3-Conclusion

After comparing both tables, particulary the Mean Difference and SD of Diferences where the Device's measurements were compared against the observer's measurements, we can affirm that the results obtained on the test performed in Multifunction Keito K7, are very similar. Therefore, from ourp ointo f view, we affirm that the comparation of the results have determined the substantial equivalence with the predicate Keito K5(K984083). The Multifunction Keito K6 and K8 have the same blood pressure modules as the Keito K7.

7.2-Body Fat Measurement comparison with TANITA TBF-300.

Summary of measurements								
Device	Number of Observations	Range Min	Max	Error Medium	Std. deviation	% Of measures with a difference greater than 2	3	4
% Fat Tanita	177	8.4	44.7	-0.4	2.2	36.7%	17.5%	0.6%
% Fat Keito K8	177	10.2	45.8					
Stadistics				Average	Std. deviation			
Age	177	18	82	39	14.7			
Starure (cm)	177	145	194	167.2	9.3			
Weight in kg	177	43.3	110.8	68.7	13.3			
		Male	Female	%Male	%Female			
Sex	177	79	98	44.6%	55.4%			

Table 6- BIA Test Keito K8 vs TANITA TBF-300

7.2.1-Conclusion

We conducted a comparative study to demonstrate that the results obtained by TANITA and Multifunction Keito device are very similar, without great differences. Not finding a standard that fixes the allowed parameters where both devices could be compared with, we have only to contrast the results and establish a comparative table to specify the differences between them. From our understanding, the effectiveness and data collected in Multifunction Keito device can be considered as safe and accurate as TANITA TBF-300 because the error Medium and the calculated Standard Deviation give us and idea of proximity and few dispersion between the measures obtained. The Multifunction Keito K6 and K7 have the same BIA modules as the Keito K8.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 10 2011

Aguiflai Iberica, S.L.
c/o Mr. Xavier Casals
Administrative Quality Department
C/ De La Pujada, 19 Poligono Industrial Els Garrofers
Vilassar de Mar, Barcelona 08340
SPAIN

Re: K103058
Trade/Device Names: Multifunction Keito, with models Keito K6, Keito K7 and Keito K8
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN, MNW
Dated: October 20, 2011
Received: October 31, 2011

Dear Mr. Casals:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

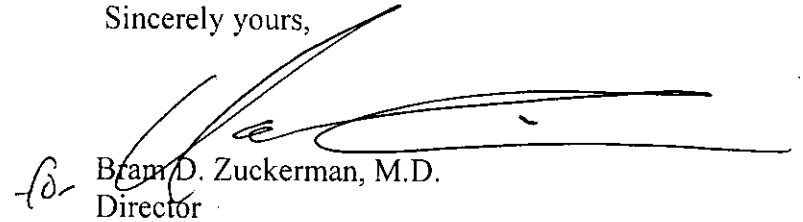
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103058

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510(K) Number (if known): K103058

Device Name: MULTIFUNCTION KEITO K6, K7 & K8

Sponsor's Name: Aguiflai Ibérica s.l.

Indications for use:

The Multifunction Keito devices are intended to be used by general public without prescription, operated with coins, to measure personal health parameters such as weight, height, estimation of body fat index, blood pressure, and pulse rate. Multifunction Keito can be installed in pharmacies or in other public sites. It is not a diagnostic device, and only offers data that users can consult with their personal physicians. The results are either printed on a ticket or saved on a card.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☐

Over-The-Counter Use ☑

(Division Sign-Off)
Division of Cardiovascular Dev...

510(k) Number K103058